Specification

1. Title of the Invention

Filler material for living tissue

2. Claims

1. A filler material for living tissue, characterized in comprising a composite material of collagen sponge and a bioabsorbable polymer material.

2. A filler material for living tissue in accordance with Claim 1, characterized in that a fibrous bioabsorbable polymer material is mixed into or embedded in the collagen sponge.

3. A filler material for living tissue in accordance with Claim 1 or Claim 2, characterized in that the bioabsorbable polymer material is poly-L-lactic acid.

3. Detailed Description of the Invention

(Industrial Applicability)

The present invention relates to a filler material which may be employed in the surgical treatment of wounds and defects and the like or in orthopedic surgery.

(Background Art)

In the surgical treatment of wounds or defects or the like, and in orthopedic surgery, filler material is embedded in damaged areas in order to regenerate tissue and to prevent contracture.

It is required of such materials that they have little reactivity with tissue, that they promote the proliferation of fibroblasts, and that they maintain their strength and shape over a long period of time until the tissue is regenerated. Furthermore, it is a particularly required property that such materials maintain their shape in order to prevent contracture of the tissue

during actual use, and additionally, that they rapidly disappear from within the body and do not remain as a foreign object after the regeneration of the tissue.

Microporous collagen sponges have been proposed for such purposes; however, they do not have the above properties.

(Problem to be Solved by the Invention)

That is to say, collagen sponges in which, for example, glutaraldehyde is cross-linked do not maintain the requisite long-term shape and strength required for use in treatment, and within two to three months of three implantation in the body, they are completely broken down and absorbed by the body and disappear.

The present invention solves the defects present in the prior art; it provides a novel filler material having little reactivity with tissue and which promotes the propagation of fibroblasts, maintains its shape and strength over a long period of time, and furthermore is absorbed into the body after treatment.

(Means for Solving the Problem)

Moreover, the present invention is characterized in that it comprises a composite material consisting of collagen sponge and a biodegradable polymer material, fibrous poly-L-lactic acid is employed as the biodegradable polymer material, and this material is mixed into or embedded in the collagen sponge.

(Function)

By combining poly-L-lactic acid, which is slow to degrade within the body, with the collagen sponge, the present invention makes it possible to maintain the structural pores of the sponge over a long period of time, and furthermore, to promote the propagation of fibroblasts in

the interior of the material by means of the combination with fibrous poly-L-lactic acid, and also to maintain the strength and shape over the long period of time required for treatment.

Hereinbelow, the composition will be described.

(Embodiment)

0.3 g of 3-Denier poly-L-lactic acid fibers (molecular weight 80,000) were twined in a sliver, and placed in a vessel having length, width, and height dimensions of 6 x 2 x 2 cm, and this was agitated for a period of 60 minutes at 1,800 rpm with 50 g of a 0.3% hydrochloric acid solution of porcine atherocollagen. Next, this was freeze-dried for a period of 48 hours and sterilized in alcohol to produce the filler material of the present invention.

The filler material obtained in this manner had the appearance of a composite in which poly-L-lactic acid fibers were randomly embedded in a microporous sponge structure.

Furthermore, as shown in Table 1, in comparison with the prior art sponge composed only of collagen, the rupture strength, rupture ductility, and Young's modulus of the present invention are considerably higher, and it represents a dramatic improvement. Furthermore, the pore size is larger.

The comparative example in the Table is a sponge comprising only collagen that was prepared by a method identical to that described above using 50 g of a 0.2% hydrochloric acid solution of porcine atherocollagen, using glutaraldehyde as a crosslinking agent.

Table 1

	Strength	Ductility	Young's Modulus	Pore Size
Present invention	7.7	132	27.8	97
Comparative Example	1.3	40	8.0	63

These values were obtained by the JIS methods. Furthermore, the units are as given below.

Strength: rupture strength (x 10^5) (dyne/cm^2)

Ductility: rupture ductility (%)

Young's Modulus: (x 10^5) (dyne/cm^2)

Pore Size: (μm)

The filler material of the present invention obtained by the method described above was employed in animal testing using the following methods, and the histology, strength, and state of contracture thereof were assessed.

(Applied Example)

A 2 x 2 cm section of the back muscle of a 350 g Wistar rat was removed, and an approximately 2 cm section of the filler material of the present invention was implanted at this spot, and the progress thereof was observed.

(After One Month)

The infiltration of fibroblasts into the peripheral portions of the sponge was confirmed, but the cells had not infiltrated into the central portion thereof.

(After Three Months)

The cellular infiltration into the central section of the sponge was increased in comparison with after two months.

(After Six Months)

In portions of the central part of the sponge, the fibroblasts were arranged in a single direction.

Histologic studies revealed that fibroblasts had sufficiently penetrated the central part of the sponge three to four months after implantation, and the tissue was completely regenerated after six months.

The state of contracture was assessed using a method in which the volume was measured by means of plaster modeling. Using the comparative example above, only approximately 5-15% of the initial volume remained after two months, and after four months, the absorption into the body was complete, and the material had disappeared. In contrast, using the filler material of the present invention, 35-50% of the original volume was present, even after six months, and this represents a striking difference.

(Effects of the Invention)

As is clear from the effects obtained when the filler material of the present invention was applied, as described above, the material has the required properties for use and does not react with tissue, promotes the propagation of fibroblasts, maintains its strength and shape over a long period of time until the regeneration of the tissue, functions to prevent contracture of the tissue, and is broken down and absorbed into the body after the regeneration of tissue, so that the material has all the properties necessary for use, and may be effectively employed.

The proportions in which the collagen sponge and the bioabsorbable polymeric material are combined, as well as the size of the poly-L-lactic acid fibers and the like may be appropriately selected in accordance with the required properties.

As described above, the present invention provides a biodegradable filler material having a novel composition which was not conventionally available.